

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Not yet assigned  
Group : Not yet assigned  
Applicants : Karin Mölling et al.  
Application No. : Not yet assigned  
Confirmation No. : Not yet assigned  
Filed : Concurrently herewith  
For : PHARMACEUTICAL COMPOSITIONS FOR TREATING  
OR PREVENTING CANCER

New York, New York  
January 15, 2002

Hon. Commissioner for Patents  
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to examining this application, kindly amend the application as follows:

IN THE CLAIMS:

Amend claims 4-7, 9-11, and 13-14 as follows\*:

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\* An "Appendix" is enclosed herewith, showing the amendments to claims 4-7, 9-11, and 13-14. In the Appendix, the additions are underscored and deletions are bracketed.

4. (Amended) The pharmaceutical composition of claim 1, in which the nucleic acid molecule encoding the tumor-associated antigen is under the control of the CMV early promoter.

5. (Amended) The pharmaceutical composition of claim 1, in which the nucleic acid molecule is a double stranded circular or linear molecule.

6. (Amended) The pharmaceutical composition of claim 1, in which the nucleic acid molecule is naked DNA.

7. (Amended) The pharmaceutical composition of claim 1, wherein the tumor-associated antigen is a gp100 protein.

9. (Amended) The pharmaceutical composition of claim 1, which further comprises one or more peptides, each comprising a region corresponding to a putative cytotoxic T cell, helper T cell or B cell epitope of a tumor-associated antigen, said peptides having the same or different amino acid sequences.

10. (Amended) The pharmaceutical composition of claim 9, which is for the administration to humans and in which the peptide(s) is (are) derived from a non-human tumor-associated antigen.

11. (Amended) The pharmaceutical composition of claims 1 or 10, in which the peptide-pulsed cells are dendritic cells.

13. (Amended) A method for treatment or prevention of cancer comprising the step of administering a nucleic acid molecule encoding a tumor-associated antigen in combination with at least one peptide comprising a region corresponding to a putative cytotoxic T cell, helper T cell or B cell epitope of a tumor-associated antigen and/or cells pulsed in vitro with at least one said peptide to a subject in need of treatment or prevention of cancer.

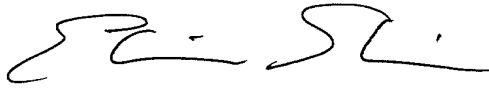
14. (Amended) The method according to claim 13, wherein the tumor-associated antigen is a gp100 protein and the cancer is a melanoma.

REMARKS

Applicants have amended claims 4-7, 9-11, and 13-14 to improve their form and/or remove improper multiple dependencies.

Entry of the amendments is requested.

Respectfully submitted,



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## APPENDIX

4. (Amended) The pharmaceutical composition of [any one of claims 1-3] claim 1, in which the nucleic acid molecule encoding the tumor-associated antigen is under the control of the CMV early promoter.

5. (Amended) The pharmaceutical composition of [any one of claims 1 to 4] claim 1, in which the nucleic acid molecule is a double stranded circular or linear molecule.

6. (Amended) The pharmaceutical composition of [any one of claims 1 to 5] claim 1, in which the nucleic acid molecule is naked DNA.

7. (Amended) The pharmaceutical composition of [any one of claims 1 to 6] claim 1, wherein the tumor-associated antigen is a gp100 protein.

9. (Amended) The pharmaceutical composition of [any one of claims 1 to 8] claim 1, which further comprises one or more [peptide] peptides, each comprising a region corresponding to a putative cytotoxic T cell, helper T cell or B cell epitope of a tumor-associated antigen, said peptides having the same or different amino acid sequences.

10. (Amended) The pharmaceutical composition of [any one of claims 1 to 9] claim 9, which is for the administration to humans and in which the peptide(s) is (are) derived from a non-human tumor-associated antigen.

11. (Amended) The pharmaceutical composition of [any one of claims 1 to 10] claims 1 or 10, in which the peptide-pulsed cells are dendritic cells.

13. (Amended) [Use of] A method for treatment or prevention of cancer comprising the step of administering a nucleic acid molecule encoding a tumor-associated antigen in combination with at least one peptide comprising a region corresponding to a putative cytotoxic T cell, helper T cell or B cell epitope of a tumor-associated antigen and/or

cells pulsed in vitro with [said] at least one said peptide [for the preparation of a pharmaceutical composition for the] to a subject in need of treatment or prevention of cancer.

14. (Amended) The [use of] method according to claim 13, wherein the tumor-associated antigen is a gp100 protein and the cancer is a melanoma.